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No. 08-887

In The
Supreme Court of the United States

COUNTY OF SAN DIEGO, et al.,

Petitioners,

vs.

SAN DIEGO NORML, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The California Court Of Appeal, Fourth Appellate District, Division One

BRIEF OF THE DRUG FREE AMERICA FOUNDATION, INC., THE DRUG FREE SCHOOLS COALITION, SAVE OUR SOCIETY FROM DRUGS, THE INTERNATIONAL SCIENTIFIC AND MEDICAL FORUM ON DRUG ABUSE, THE INSTITUTE ON GLOBAL DRUG POLICY, STUDENTS TAKING ACTION NOT DRUGS, SAFE APPROVED MEDICINE FOR NEW JERSEY AND VARIOUS CALIFORNIA ORGANIZATIONS AND CITIZENS, ET AL., AS AMICI CURIAE IN SUPPORT OF PETITIONER

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QUESTIONS PRESENTED

Whether California's Medical Marijuana Law, which authorizes individuals to use, possess and cultivate marijuana for medical purposes, is pre-empted under the Supremacy Clause by the federal Controlled Substances Act, which prohibits the same conduct?

Whether the Controlled Substances Act's express preemption clause precludes a court from considering whether California's Medical Marijuana Law is an obstacle to the accomplishment of the purposes and objectives of the federal law in deciding whether the California law is preempted?

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INTEREST OF AMICI

Amici Curiae are parents who have lost children to drugs, and drug-prevention organizations, distinguished medical and scientific experts, policy makers, business owners and others who are concerned with preventing drug abuse.[1] They share a common concern that smoked or crude marijuana is disingenuously referred to as medicine.[2] Smoked or "crude" marijuana is a dangerous Schedule I drug, notwithstanding creative attempts by those who seek its legalization to label its use as "compassionate" in medical settings. "Medical" marijuana initiatives now enacted in several states undermine our national drug-enforcement priorities as provided in the Controlled Substances Act and our well-designed federal

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[1] The parties have consented to the filing of this brief. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the Amici Curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

[2] Throughout this brief we use the term "crude marijuana" to describe the illicit Schedule I drug that people abuse. The drug is derived from the leaves and flowering tops of the Cannabis plant and is consumed in a variety of ways. The dried plant material is most often rolled in paper and smoked as a cigarette, called a "joint." It is often placed in smoking devices called "bongs," smoked in pipes, or smoked in "blunts," which are cigars from which the tobacco has been removed and replaced with marijuana plant material. Sometimes it is baked in cookies or brownies and eaten, or brewed in tea and drunk. Other methods for consuming the drug are constantly being developed by the drug culture, including versions that allegedly aerosolize crude marijuana to remove its "tars."

system of approval of new drugs. We must preserve the Food and Drug Administration's medical and scientific drug approval process that protects Americans from unsafe, ineffective drugs. This brief is submitted to present to the Court current research which confirms that the drug marijuana continues to have no currently accepted medical use and that the California "medical" marijuana law is an obstacle to the accomplishment of the purposes and objectives of the federal law.

The complete list of amici is in Appendix I

This brief is in memory of the following dear children lost to drugs.

Dave and Casey Pease

Steven Steiner, Jr., age 19

Garrett Douglas Hughes, age 22

David Farmer, age 28

Karen Lynn Berry, age 17

Daniel R. Silverman, age 19

SUMMARY OF ARGUMENT

There is still no proven medical value in the use of crude marijuana. This remains the unequivocal position of the Food and Drug Administration, which is charged by Congress with making this determination. Absent a legitimate and currently accepted

medical use for crude marijuana, the lower court's reasoning must fail, as it would therefore have no basis for establishing this separate class of drug use which is independent of the Controlled Substances Act. As demonstrated herein, both federal law and the weight of medical research continue to find crude marijuana use to be dangerous and without legitimate medical application. In addition, the California medical marijuana law has led to widespread abuses.

ARGUMENT I

BECAUSE CRUDE MARIJUANA HAS NO CURRENTLY ACCEPTED MEDICAL USE, ITS PURPORTED MEDICAL USE CANNOT CONSTITUTE A CLASS OF ACTIVITIES SEPARATE FROM THE ACTIVITIES REGULATED BY THE CONTROLLED SUBSTANCES ACT ("CSA"), AND THE CSA, PURSUANT TO THE COMMERCE CLAUSE POWERS, HAS JURISDICTION OVER ANY AND ALL MARIJUANA USE

There is a strong governmental interest in prohibiting the distribution of crude marijuana as medicine. The federal government has expressly taken on the job of protecting our citizens from unsafe, ineffective substances sold as "medicines," and from drug abuse, drug addiction, and the abusive and criminal behaviors that marijuana and other illicit drugs often generate. Before any drug can be classified as "medicine," the drug must first be approved by the Food and Drug Administration (the "FDA"). The federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 351-360,

gives the federal government, through the FDA, sole responsibility for determining that drugs are safe and effective, a requirement all medicines must meet before they may be distributed to the public. The FDA has not approved crude marijuana as safe or effective, so the drug may not legally be prescribed and sold as a medicine.

Not only has the FDA failed to approve marijuana, but Congress has classified marijuana as a Schedule I controlled substance under the Controlled Substances Act. Schedule I drugs have "(1) a high potential for abuse, (2) no currently accepted treatment in the United States, and (3) a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(f). The classification of marijuana as a Schedule I drug has been repeatedly challenged and the challenges repeatedly rejected. *Gonzales v. Raich*, 545 U.S. 1, 15 n.23 (2005). Indeed, according to federal law, "medical marijuana" is a non sequitur. It cannot be reanimated, phoenix-like, at the state level, simply to create an otherwise unavailable refuge from the scope of the CSA.

In *Alliance for Cannabis Therapeutics v. DEA and NORML v. DEA,* 15 F.3d 1131 (D.C. Cir 1994), the United States District Court for the District of Columbia accepted the Drug Enforcement Administration's new five-part test for determining whether a drug is in "currently accepted medical use." Id. at 1135. The test requires that:

(1) The drug's chemistry must be known and reproducible;

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available.

Applying these criteria to a petition to reschedule crude marijuana, the court found that the drug had no currently accepted medical use and, therefore, must remain a Schedule I substance. It should be noted that although the FDA has not approved crude marijuana as safe and effective, the FDA has approved medications to treat all of the diseases, symptoms, and ailments identified in California's medical marijuana law, and therefore, safe and effective legal alternatives to crude marijuana exist.

All medications, particularly those containing controlled substances, should become available only after having satisfied the rigorous criteria of the federal Food and Drug Administration (FDA) approval process. That process has been carefully constructed over the past century to protect patient health and safety. Patients and physicians have the right to insist that prescription medications have satisfied modern medical standards for quality, safety and efficacy. Such medications must be standardized by composition and dose and administered in an appropriate delivery system with a reproducible dose. Furthermore, preclinical and clinical studies are

necessary to provide physicians with adequate information to guide their prescribing decisions.

The anecdotal reports of benefits of "medical" marijuana cannot be regarded as scientific evidence because the claimed benefits were not independently verified and quantified. The anecdotal reports do not reflect double-blind controls and hence are not free of potential confounders such as expectancy, placebo effect, and deliberate exaggeration for ideological reasons.[3]

There is no reason why medications derived from the cannabis plant should be exempted from the FDA process. Proliferation of "medical marijuana" state laws creates an unregulated system that allows untested and potentially contaminated materials to be distributed to vulnerable patients.

"Medical" marijuana is not dispensed in medically controlled environments nor are the "patients" required to be monitored by physicians after they obtain the recommendation. In many cases the "patients" are not even examined by physicians. Such a system benefits marijuana growers and vendors, but endangers the well-being of patients and undermines the integrity of the physician-patient relationship.

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[3] "Smoked Marijuana as Medicine: Not Much Future," Clinical Pharmacology & Therapeutics (2008), H Kalant, Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada

Many prominent national health organizations do not support crude smoked marijuana for medicinal use. Crude marijuana as medicine has been rejected by the American Medical Association, the National Multiple Sclerosis Society, the American Glaucoma Society, the American Academy of Ophthalmology, the American Cancer Society, the National Eye Institute, the National Institute for Neurological Disorders and Stroke and the federal Food and Drug Administration.[4]

Some medical organizations, such as the American College of Physicians, support research into cannabinoids. This has been used by marijuana legalization advocates as proof that these organizations support crude marijuana – but this is not accurate. For example, the ACP supported research into cannabinoids such as THC but they specifically stated "The ACP encourages the use of nonsmoked forms of THC that have proven therapeutic value." It must be non-smoked and it must have proven value such as being approved by the FDA.[5]

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[4] Bonner, R., Marijuana Rescheduling Petitions, 57 Federal Register 10499-10508; *Alliance for Cannabis Therapeutics v. DEA and NORML v. DEA*, 15 F.3d 1131 (D.C. Cir 1994)

Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is Medicine – The U.S. Food and Drug Administration, 20 April 2006, www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html

[5] Supporting Research into the Therapeutic Role of Marijuana, American College of Physicians, 2008

The supporters of "medical" marijuana want to confuse support for research into specific chemicals in marijuana with support for smoked marijuana as a medicine. There is some scientific interest in the exploration of the therapeutic uses for some of the individual chemicals in marijuana. However, we must distinguish between the exploration of the therapeutic potential of these chemicals with support for smoking as a delivery system for these chemicals. No reputable medical organization has come out in favor of smoking marijuana as a good or preferred delivery method.

Drs. Eric Voth and Richard Schwartz, experts on marijuana, having extensively reviewed available therapies for chemotherapy-associated nausea, glaucoma, multiple sclerosis, and appetite stimulation, determined that no compelling need exists to make crude marijuana available as a medicine for physicians to prescribe. They concluded that the most appropriate direction for research is to research specific cannabinoids or synthetic analogs rather than pursuing the smoking of marijuana.[6]

The conclusions of Drs. Voth and Schwartz were echoed by the National Academy of Science's Institute of Medicine (hereinafter IOM Report) in an assessment of scientific marijuana and cannabinoid research.

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[6] Voth EA, Schwartz RH. Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana. *Annals of Internal Medicine* 1997;126:791-798.

They see "little future in smoked marijuana as a medicine."[7]

There are safe medicines available

Legalization advocates would have the public and policy makers incorrectly believe that marijuana is the only treatment alternative for masses of cancer sufferers who are going untreated for the nausea associated with chemotherapy, and for all those who suffer from glaucoma, multiple sclerosis, and other ailments. However, numerous effective medications are currently available for these conditions. The advocates of "medical" marijuana list cancer, epilepsy, spasticity, and AIDS as conditions for which "medical" marijuana can be used. According to Dr. Eric Voth, a Fellow of the American College of Physicians, the only use for cancer treatment is the nausea associated with chemotherapy, or appetite stimulation, but there are better FDA approved medications available. There are no uses for treating epilepsy. With AIDS it has been claimed to help appetite but there are better safer FDA medications for this. The only remotely

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[7] *Marijuana and Medicine: Assessing the Science Base.* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health, Institute of Medicine, National Academy of Sciences. National Academy Press, Washington D.C., 1999; http://www.nap.edu/html/marimed

documented benefit is with spasticity but there are better medicines available.[8]

For example, below is a list of the FDA approved medications currently available for chemotherapy, and other ailments.

Serotonin Antagonists
Ondansetron (Zofran)
Granisetron (Kytril)
Tropisetron (Navoban)
Dolasetron
Phenothiazines
Prochlorperazine (Compazine)
Chlorpromazine (Thorazine)
Thiethylperazine (Torecan)
Perphenazine (Trilafon)
Promethazine (Phenergan)
Corticosteroids
Dexamethasone (Decadron)
Methylprednisolone (Medrol)
Anticholinergics
Scopolamine (Trans Derm Scop)
Butyrophenones
Droperidol (Inapsine)

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[8] The Potential Medical Liability for Physicians Recommending Marijuana as a Medicine, Educating Voices, http://www.educatingvoices.org (go to bottom of web page); Brief of the Institute on Global Drug Policy of the Drug Free America Foundation; National Families in Action; Drug Watch International; Drug-free Kids: America's Challenge, et al., as Amici Curiae in Support of Petitioner 2001 WL 30659 (Jan. 10, 2001), *U.S. v. Oakland Cannabis Buyers' Cooperative*, 121 S.Ct. 1711 (2001); a cannabinoid based medicine named Sativex is currently working its way through the FDA process.

Haloperidol (Haldol)
Domperidone (Motilium)
Benzodiazepines
Lorazepam (Ativan)
Alprazolam (Xanax)
Substituted Benzamides
Metoclopramide (Reglan)
Trimethobenzamide (Tigan)
Alizapride (Plitican)
Cisapride (Propulsid)
Antihistamines
Diphenhydramine (Benedryl)[9]

Marijuana legalization advocates would have you believe that crude marijuana is "medicine" and not a harmful drug. The scientific studies state the contrary. Recent studies show the following destructive effects of using marijuana:

birth defects
the worsening of pain
lung damage
causes cancer including in children and testicular cancer
AIDS – marijuana opens the door to Kaposi's sarcoma
brain damage

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[9] Brief of the Institute on Global Drug Policy of the Drug Free America Foundation; National Families in Action; Drug Watch International; Drug-free Kids: America's Challenge, et al., as Amici Curiae in Support of Petitioner 2001 WL 30659 (Jan. 10, 2001), U.S. v. Oakland Cannabis Buyers' Cooperative, 121 S.Ct. 1711 (2001); List reconfirmed by Dr. Eric Voth on May 14, 2006.

strokes
immune system damage
mental illness
violence
infertility
addiction[10]

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[10] Risk of Selected Birth Defects with Prenatal Illicit Drug Use, Hawaii, 1986-2002, *Journal of Toxicology and Environmental Health*, Part A, 70: 7-18, 2007; "Too Much Cannabis Worsens Pain" – *BBC News*, 24 October 2007; "Study Finds that Marijuana Won't Stop Multiple Sclerosis Pain" – *Neurology*, 2002; 58:1404-1407; Marijuana Smoke Contains Higher Levels of Certain Toxins Than Tobacco Smoke, *Science Daily*, December 18, 2007; Marijuana Smokers Face Rapid Lung Destruction – As Much as 20 Years Ahead of Tobacco Smokers, *Science Daily*, January 27, 2008; "Use of Marijuana Impairs Lung Function" – *Addiction*, 2002; 97:1055-1061; "Respiratory and Immunologic Consequences of Marijuana Smoking" – *Journal of Clinical Pharmacology*, 2002; 42:71S-81S; "Association Between Marijuana Use and Transitional Cell Carcinoma" – *Adult Urology*, 2006; 100-104; Maternal Use of Recreational Drugs and Neuroblastoma in Offspring: a Report from the Children's Oncology Group (United States) Cancer Causes Control, 2006 Jun;17(5):663-9; Marijuana may Raise Testicular Cancer Risk: Study, Reuters, February 9, 2009; "Marijuana Component Opens The Door For Virus That Causes Kaposi's Sarcoma" – *Science Daily*, 2 August 2007; "Marijuana May Affect Blood Flow in Brain" – *Reuters*, 7 February 2005; "More Evidence Ties Marijuana to Stroke Risk" – Reuters Health, 22 February 2005; "Immunological Changes Associated with Prolonged Marijuana Smoking" – American College of Allergy, *Asthma and Immunology*, 17 November 2004; "Cannabis-Related Schizophrenia Set to Rise, Say Researchers" – *Science Daily*, 26 March 2007; "Report: Using Pot May Heighten Risk of Becoming Psychotic" – *Associated Press*, 26 July 2007; "Anterior Cingulate Grey-Matter Deficits and Cannabis Use in First-Episode Schizophrenia" – *The British Journal of Psychiatry*, 2007; 190: 230-236; "Marijuana Increases

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Smoking is a very poor way to deliver medicine. The smoking of marijuana has significant risks. It is difficult to administer safe, regulated dosages of medicines in smoked form. Furthermore, the harmful

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the Risk of Both Psychosis In Non-Psychotic People As Well As Poor Prognosis For Those With Risk of Vulnerability to Psychoses" – *American Journal of Epidemiology*, 2002; 156:319-327; "Psychophysiological Evidence of Altered Neural Synchronization in Cannabis Use: Relationship to Schizotypy" – *Am J Psychiatry*, 2006; 163:1798-1805; "Marijuana Linked to Schizophrenia, Depression" – *British Medical Journal*, 21 November 2007; "Cannabis Shows Anti-Depression Benefits But Too Much Has Reverse Effect" – *The Canadian Press*, 24 October 2007; "Differential Effects of Delta-9-THC On Learning in Adolescent and Adult Rats" – *Pharmacology Biochemistry and Behavior*, 2 May 2006; The Occurrence of Cannabis Use Disorders and Other Cannabis Related Problems Among First Year College Students, *Addictive Behaviors* 33(3):397-411, March 2008; "Marijuana Firmly Linked to Infertility" – *Scientific American*, 22 December 2000; The Occurrence of Cannabis Use Disorders and Other Cannabis Related Problems Among First Year College Students, *Addictive Behaviors* 33(3):397-411, March 2008; "Regular or Heavy Use of Cannabis Was Associated with Increased Risk of Using Other Illicit Drugs" – *Addiction*, 2006; 101:556-569; "As Marijuana Use Rises, More People Are Seeking Treatment for Addiction" – *Wall Street Journal*, 2 May 2006; "Adolescent Cannabis Exposure Alters Opiate Intake and Opioid Limbic Neuronal Populations in Adult Rats" – *Neuropsychopharmacology*, 2006, 1-9; "Twenty-Five Year Longitudinal Study Affirms Link Between Marijuana Use and Other Illicit Drug Use" – Congress of the United States,14 March 2006; "New Study Reveals Marijuana is Addictive and Users Who Quit Experience Withdrawal" – All Headline News, 6 February 2007

chemicals and carcinogens that are byproducts of smoking create entirely new health problems.[11]

The respiratory difficulties associated with marijuana use preclude the inhaled route of administration as a medicine. Smoked marijuana is associated with higher concentrations of tar, carbon monoxide, and carcinogens than even cigarette smoke.[12] Marijuana adversely impairs some aspects of lung function, causes abnormalities in the cells lining the airways of the upper and lower respiratory tract and in the airspaces deep within the lung, and has been associated with the development of cancer.[13]

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[11] Brief of the Institute on Global Drug Policy of the Drug Free America Foundation; National Families in Action; Drug Watch International; Drug-free Kids: America's Challenge, et al., as Amici Curiae in Support of Petitioner 2001 WL 30659 (Jan. 10, 2001), *U.S. v. Oakland Cannabis Buyers' Cooperative*, 121 S.Ct. 1711 (2001)

[12] Wu et al., Pulmonary hazards of smoking marijuana as compared with tobacco, NEJM, 1988:318:347-351.

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In addition to these cellular abnormalities and consequences, contaminants of marijuana smoke are known to include certain forms of bacteria and fungi. Those at particular risk for the development of disease and infection when these substances are inhaled, are those users with impaired immunity such as those with AIDS.[14]

Smoking marijuana can cause intoxication, precipitation of anxiety or acute psychotic reactions, orthostatic hypotension and bronchial inflammation. For a drug to be acceptable, its beneficial results must outweigh the adverse effects, especially when

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habitual smoking of marijuana alone and with tobacco on nonspecific airways hyperreactivity, *Journal of Psychoactive Drugs* 1988:20:21-25; Tilles et al., Marijuana smoking as cause of reduction in single-breath carbon monoxide diffusing capacity, *American Journal of Medicine* 1986:80:601-606; Barbers et al., Chemotaxis of peripheral blood and lung leukocytes obtained from tobacco and marijuana smokers, *Journal of Psychoactive Drugs* 1988:20:15-20; Buckley, A case-control study of acute non-lymphoblastic leukemia: evidence for an association with marijuana exposure, Cannabis: Physiopathology, Epidemiology, Detection pp. 155-162 (CRC Press 1993); Murison et al., Cannabinoids induce incomplete maturation of cultured human leukemia cells, Proc Natl Acad Sci USA 1987:84:55414-5418; *Robison et al., Maternal drug use and risk of childhood non-lymphoblastic leukemia among offspring, Cancer* 1989:63:1904-1911.

[14] Fleisher, Winawer & Zauber, Aspergillosis and marijuana, Annals of Internal Medicine 1991:115:578-579; Ramirez, Acute pulmonary histoplasmosis: newly recognized hazard of marijuana plant hunters, *American Journal of Medicine* 1990:88:5-60N-5-62N; Taylor et al., Salmonellosis associated with marijuana: a multi state outbreak traced by plasmid fingerprinting, NEJM 1982:306:1249-1254.

the claim is that it can be used repeatedly for symptomatic relief of chronic disorders.[15]

In recent years there has been a great public effort to curtail tobacco because of its effects on health yet the advocates of legalization promote smoking marijuana. Yet, a recent study shows that marijuana smoke has ammonia levels 20 times higher than tobacco smoke. Marijuana has hydrogen cyanide, nitric oxide, and aromatic amines at 3-5 times higher than tobacco smoke.[16] Another study shows that that marijuana smokers face rapid lung destruction – as much as 20 years ahead of tobacco smokers.[17]

Amici assert that in the interest of protecting seriously and terminally ill patients from unsafe and ineffective drugs, the safety and efficacy process of the FDA cannot be bypassed. The FDA has thoroughly examined the possible use and/or re-classification of crude marijuana, and it has correctly determined that crude marijuana is an impure and toxic substance that has no place in the medical armamentarium.

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[15] "Smoked Marijuana as Medicine: Not Much Future," *Clinical Pharmacology & Therapeutics* (2008), H Kalant, Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada

[16] Marijuana Smoke Contains Higher Levels of Certain Toxins Than Tobacco Smoke, *Science Daily*, December 18, 2007

[17] Marijuana Smokers Face Rapid Lung Destruction – As Much as 20 Years Ahead of Tobacco Smokers, *Science Daily*, January 27, 2008

Furthermore, by means of its appropriate regulatory processes, the FDA remains available to petitioning for reclassification, should sufficient evidence for such change of classification arise. To date, it has not. On April 20, 2006, the FDA issued the following Statement, released in response to a congressional debate on the issue of medical marijuana use:

FDA STATEMENT – INTER-AGENCY ADVISORY REGARDING CLAIMS THAT SMOKED MARIJUANA IS A MEDICINE

> Claims have been advanced asserting smoked marijuana has a value in treating various medical conditions. Some have argued that herbal marijuana is a safe and effective medication and that it should be made available to people who suffer from a number of ailments upon a doctor's recommendation, even though it is not an approved drug.
>
> Marijuana is listed in schedule I of the Controlled Substances Act (CSA), the most restrictive schedule. The Drug Enforcement Administration (DEA), which administers the CSA, continues to support that placement and FDA concurred because marijuana met the three criteria for placement in Schedule I under 21 U.S.C. 812(b)(1) (e.g., marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety for use under medical supervision). Furthermore, there is currently sound evidence that smoked marijuana is

harmful. A past evaluation by several Department of Health and Human Services (HHS) agencies, including the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute for Drug Abuse (NIDA), concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.

FDA is the sole Federal agency that approves drug products as safe and effective for intended indications. The Federal Food, Drug, and Cosmetic (FD&C) Act requires that new drugs be shown to be safe and effective for their intended use before being marketed in this country. FDA's drug approval process requires well-controlled clinical trials that provide the necessary scientific data upon which FDA makes its approval and labeling decisions. If a drug product is to be marketed, disciplined, systematic, scientifically conducted trials are the best means to obtain data to ensure that drug is safe and effective when used as indicated. Efforts that seek to bypass the FDA drug approval process would not serve the interests of public health because they might expose patients to unsafe and ineffective drug products. FDA has not

> approved smoked marijuana for any condition or disease indication.
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> A growing number of states have passed voter referenda (or legislative actions) making smoked marijuana available for a variety of medical conditions upon a doctor's recommendation. These measures are inconsistent with efforts to ensure that medications undergo the rigorous scientific scrutiny of the FDA approval process and are proven safe and effective under the standards of the FD&C Act. Accordingly, FDA, as the federal agency responsible for reviewing the safety and efficacy of drugs, DEA as the federal agency charged with enforcing the CSA, and the Office of National Drug Control Policy, as the federal coordinator of drug control policy, do not support the use of smoked marijuana for medical purposes. www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html

Marijuana is intoxicating, so it's not surprising that sincere people report relief of their symptoms when they smoke it. They may be feeling better – but they are not actually getting better. They may even be getting worse due to the detrimental effects of marijuana.

Before the development of modern pharmaceutical science, the field of medicine was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. Thus evolved our current Food and Drug Administration and drug scheduling processes, which

Congress has authorized in order to create a uniform and reliable system of drug approval and regulation. This system is being intentionally undermined by the legalization proponents through use of medical marijuana initiatives.

ARGUMENT II

IT IS INEVITABLE THAT MARIJUANA PRODUCED FOR MEDICINAL USE WILL FALL INTO THE HANDS OF RECREATIONAL DRUGS USERS BECAUSE RECREATIONAL DRUG USERS WILL EXPLOIT THE LAWS IN ORDER TO OBTAIN A MARIJUANA RECOMMENDATION THUS MAKING IT EVEN MORE DIFFICULT TO ACHIEVE THE GOAL OF CONGRESS TO ELIMINATE THE USE OF MARIJUANA

The amount of marijuana permitted by the "medical" marijuana law exceeds any reasonable amount. In 2003, the California Legislature passed a statutory scheme to implement Proposition 215. Cal. Health & Safety Code §§ 11362.7-11362.83. The Legislature authorized patients and caregivers to grow six mature marijuana plants. *Id.* at § 11362.77(a). If a doctor recommends more, the quantity can be increased to an amount "consistent with the patient's needs." Cal. Health & Safety Code § 11362.77(b). Six plants can create a huge amount of marijuana. The typical marijuana plant produces 1 to 5 pounds of smokeable materials (leaves and buds). Maybe more if grown indoors under the right conditions. The 6

plants permitted by the bill can thus produce a minimum of 6 to 30 pounds of marijuana per year.[18]

A typical marijuana joint is estimated to weigh about 0.4 grams. If a standard joint is 0.4 grams of average-quality 6% marijuana buds, an ounce of "standard marijuana" equals more than 60 joints. An ounce of more potent 12% sinsemilla is 120 joints. Thus an ounce is from 60 to 120 joints.[19]

Thus, the law permits people to grow up to 6 plants per "patient" and the plants can produce 6 to 30 pounds of marijuana per year. **This is 5,760 to 28,800 joints for standard marijuana and 11,520 to 57,600 for sinsemilla per year.** This large amount of marijuana is unregulated and can easily be diverted for recreational use. What other medicine is dispensed in such huge quantities?

The California Law Is Widely Abused and Generates Citizen Outrage

Since California passed its "medical" marijuana law, more than 90 cities and counties in the state

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[18] Drug Identification Bible, third edition, page 606, Tim Marnell editor, Denver, CO, 800-772-2539 (a book for law enforcement, parents and educators)

[19] Economics of cannabis legalization, written by Dale Gieringer, Ph.D., coordinator, California NORML (National Organization for the Reform of Marijuana Laws). Reprinted from Ed Rosenthal, ed., Hemp Today pp. 311-24. (Quick American Archives, Oakland, CA 1994)

have had to pass moratoriums or bans on the distribution of marijuana in their communities. As a result of these abuses, only 24 out of California's 58 counties now issue marijuana ID cards. In North Hollywood California there are now more "medical" marijuana clubs than Starbucks outlets. Less than two years ago, there were only four marijuana dispensaries in Los Angles. Today, there are more than 100.[20]

The founders of the U.S. "medical" marijuana movement have reversed key positions of support for "medical" marijuana. Rev. Scott Imler, Co-founder of Prop. 215 the California "medical" marijuana law, has lamented the passage of the law stating that, "We created Prop. 215 so that patients would not have to deal with black market profiteers. But today it is all about the money. Most of the dispensaries operating in California are little more than dope dealers with store fronts." Imler also said that "medical" marijuana has "turned into a joke."[21]

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[20] Daily News Los Angeles, CA January 19th, 2007; Santa Cruz Sentinel, As We See It: Medical Marijuana Abuse?, March 12, 2007; What Every American Should Know About Medical Marijuana, Office of National Drug Control Policy, 750 17th St. NW, Washington, D.C. 20503 (202) 395-6618 www.WhiteHouse DrugPolicy.gov

[21] What Every American Should Know About Medical Marijuana, Office of National Drug Control Policy, 750 17th St. NW, Washington, D.C. 20503 (202) 395-6618 www.WhiteHouse DrugPolicy.gov; Alternatives Magazine, Fall, 2006 Issue 39, San Gabriel Valley Tribune 2/07, Message from Steve Kubby, Steve Kubby Released After Serving 62 Days in Jail, April 14th, 2006

The California "medical" marijuana dispensaries are out of control

The average marijuana dispensary in California makes $20,000 in profit each day. Marijuana providers buy marijuana wholesale from street dealers and resell it for twice the amount.[22] A story from the T.V. news show *60 Minutes* shows that in California "there are legions of people buying 'medical' marijuana for the sole purpose of getting high." They are getting marijuana for such conditions as dry skin, hair loss and because high heels hurt a woman's feet. According to *60 Minutes*, the "medical" marijuana they buy goes under the names of: Snow White, Super Girl, Afghan Dreams, or New York Diesel.[23]

Some examples of the problems caused by the "medical" marijuana dispensaries are:

Street level dealers attempting to sell to people entering the business

Smoking of marijuana in public areas

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[22] Glazer, Andrew. Medical Marijuana Clinics Face Crackdown, Associated Press, March 11th, 2007; Vendor's Reefer Sadness LA Times, December 27th, 2006, LA City Beat, La, Ana, February 15th, 2007; What Every American Should Know About Medical Marijuana, Office of National Drug Control Policy, 75017 th St. NW, Washington, D. C. 20503 (202) 395-6618 www.WhiteHouseDrugPolicy.gov; *Daily News* Los Angeles, CA January 19th, 2007, *Santa Cruz Sentinel*, As We See It: Medical Marijuana Abuse?, March 12, 2007

[23] California Pot Shops, Morley Safer, 60 Minutes (CBS News) 12/30/2007

Increased "driving while under the influence of marijuana" violations

Attempted burglaries of marijuana establishments

Robberies of clients as they leave businesses with their purchases

Adverse impact on neighboring businesses

Presence of a physician on the premises issuing recommendations for use, which drew numerous people from out of the area

Lack of effort on the part of dispensary owners/employees to control unlawful or nuisance behavior in and around the business

Increased loitering and associated nuisances

Complaints that other illegal drugs were sold from the dispensaries

Trading of marijuana purchased at a dispensary to a minor for sex

Purchasers congregating and smoking marijuana in areas frequented by children

Sales of marijuana to persons not holding the appropriate certificate.[24]

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[24] Memorandum from Chief David Livingston, Concord California Police Department, to the Mayor and Council Members, August 29, 2003; http://www.californiapolicechiefs.org. Then click on Medical Marijuana Dispensary Information.

CONCLUSION

Amici believe that it is critically important that the Supreme Court uphold the supremacy of the federal FDA regulatory process, and its carefully researched determination that there is no currently accepted medical use for crude, or home-grown, marijuana, and that therefore there can be no "medical use" exception to the Controlled Substances Act. Logically, then, the lower Court cannot create a distinct class of activities out of the "medical use" subgroup, and therefore the alleged medical use of marijuana is an activity which must come under the jurisdiction of the federal Controlled Substance Act, as authorized by the Commerce Clause of the U.S. Constitution. Accordingly, the decision of the lower Court should be reversed.

Respectfully submitted,

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APPENDIX I

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NM; Shirley Morgan, Oregonians Against Legalization of Marijuana, Welches, OR; Andrea G. Barthwell, MD EMGlobal LLC, Arlington, VA; Eleaner Scott, Westminster Area Community Awareness Action Team, Westminster, CO; John Lunt, DEA Supervisory Special Agent, Retired, Fort Worth, TX; David Gross, MD, Chair, International Scientific and Medical Forum on Drug Abuse; Judi Strang, San Dieguito Alliance for Drug Free Youth, Del Mar, CA; Roger Morgan and Carla Lowe, Californians For Drug-Free Schools; Betty S. Sembler, Founder and Chair, Save our Society from Drugs, FL; Calvina Fay, Executive Director Drug Free America Foundation, Inc., FL; Robert DuPont, MD, President Institute for Behavior and Health, Inc. MD; Judy Kreamer, President Educating Voices, Inc. Naperville, IL; Cornelius J. Behan, Towson, MD; Lt. Edward Moses, Ret. Founder Missouri Federation of Parents, Warrenton, MO; Peter B. Bensinger, President Bensinger, DuPont & Assoc., Chicago, IL; Tom Constantine, Superintendent NY State Police (Ret) Administrator U.S. Drug Enforcement Administration (Ret), Niskayuna, NY; Eve Flanigan, Program Manager Carlsbad Comm. Antidrug/Gang Coalition, Carlsbad, NM; Richard Bucher, PhD, the Chairman of the Board Drug Free Kids: America's Challenge, Fort Washington, MD; Linda Taylor, Exec. Director Repeal Prop 36 Fund, Turlock, CA; Theresa Costello, Port Richmond Community Group, Philadelphia, PA; Darlind Davis, Exec. Director Drug-Free Moore County, Pinehurst, NC; Janet Y. Maust, Families against Legalization, Hopwood, PA; Stephen Winkler, Goff, KS; Kathy Burson

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